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ORIGINAL REPORT

Effects of a Brief Multimedia Psychoeducational Intervention on the Attitudes and Interest of Patients With Cancer Regarding Clinical Trial Participation: A Multicenter Randomized Controlled Trial

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ABSTRACT

Purpose
The negative attitudes of patients with cancer regarding clinical trials are an important contributor to low participation rates. This study evaluated whether a brief psychoeducational intervention was effective in improving patients' attitudes as well as their knowledge, self-efficacy for decision making, receptivity to receiving more information, and general willingness to participate in clinical trials.

Patients and Methods
A total of 472 adults with cancer who had not been asked previously to participate in a clinical trial were randomly assigned to receive printed educational information about clinical trials or a psychoeducational intervention that provided similar information and also addressed misperceptions and concerns about clinical trials. The primary (attitudes) and secondary outcomes (knowledge, self-efficacy, receptivity, and willingness) were assessed via patient self-report before random assignment and 7 to 28 days later.

Results
Patients who received the psychoeducational intervention showed more positive attitudes toward clinical trials ($P = .016$) and greater willingness to participate ($P = .011$) at follow-up than patients who received printed educational information. Evidence of an indirect effect of intervention assignment on willingness to participate (estimated at 0.168; 95% CI, 0.088 to 0.248) suggested that the benefits of psychoeducation on willingness to participate were explained by the positive impact of psychoeducation on attitudes toward clinical trials.

Conclusion
A brief psychoeducational intervention can improve the attitudes of patients with cancer toward clinical trials and thereby increase their willingness to participate in clinical trials. Findings support conducting additional research to evaluate effects of this intervention on quality of decision making and rates of participation among patients asked to enroll onto therapeutic clinical trials.

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INTRODUCTION

Clinical trials represent a critical step in successful development of more effective cancer treatments. Despite their importance, completion of therapeutic clinical trials is hindered by low rates of patient participation. For example, a study of patients at a university-based cancer center found 49% declined participation even though they met eligibility criteria.[1] These figures point to the need to develop interventions that increase the likelihood patients with cancer will participate in clinical trials. Despite the need, the interventions tested, which have focused primarily on improving the consenting process, have demonstrated limited impact on clinical trial participation.[2] A criticism of much previous research is that it has not been driven by theory or in-depth understanding of patient barriers to clinical trial participation.[2]

Research has consistently identified patients' negative perceptions and attitudes about clinical trials as contributing factors to nonparticipation.[3-5] These findings are consistent with the theory of planned behavior, which stipulates that attitudes

about a behavior are a key determinant of intentions to engage in that behavior.[6] On the basis of this theory and prior research,[3-5] it can be hypothesized that interventions that improve patients' attitudes toward clinical trials will have a positive impact on their intentions to participate. Two previous studies directly evaluated this possibility; in both studies, the same 18-minute educational video served as the intervention.[7,8] One study found that among 126 patients with lung cancer who had not previously participated in a clinical trial, the video had a significant positive impact on likelihood of participating but not on attitudes.[8] The other study found that among 196 patients with breast cancer who had not previously participated in a clinical trial, the video had no significant effects on either outcome.[7]

The present study sought to evaluate the previously stated hypothesis in a more comprehensive manner by examining effects of a new brief multimedia psychoeducational intervention in a large, heterogeneous sample of patients with cancer. The first objective was to determine intervention effects on attitudes toward clinical trials. The second objective was to examine intervention effects on patients' knowledge about clinical trials, perceived ability to make a decision about participation, receptivity to learning more about clinical trials, and willingness to participate in clinical trials. The third objective was to evaluate potential mediators of intervention effects on willingness to participate if warranted by results for the first two objectives. Although information about therapeutic clinical trial participation was collected, this initial evaluation was not limited to patients eligible for a therapeutic clinical trial or designed to evaluate intervention effects on participation rates.

PATIENTS AND METHODS

Participants

Eligible patients were ≥ 18 years of age, were able to speak and read English, had been diagnosed with cancer, were scheduled for a consultation visit with a medical oncologist, and had not been asked previously to participate in a clinical trial for the treatment of cancer. Recruitment was conducted at a National Cancer Institute–designated comprehensive cancer center, a university-based cancer center, and five community-based oncology practices. The study was approved by institutional review boards for each site.

Procedures

Site coordinators reviewed records and appointments to identify potentially eligible patients. They then met with these patients just before or after the oncologist saw the patient for a consultation or just before the oncologist saw the patient at the next visit. During these meetings, coordinators confirmed eligibility, described the study, and obtained written informed consent from those wishing to participate. Immediately after, and before any potential discussion of a therapeutic clinical trial, patients completed a baseline assessment via a paper questionnaire and were randomly assigned in a one-to-one ratio to print education (PE) or multimedia psychoeducation (MP) using a centralized computerized program. Seven to 28 days after enrollment, patients were contacted by telephone at a prescheduled time to complete a follow-up assessment, during which a research associate at a central location verbally administered the same outcome measures contained in the baseline questionnaire. Six weeks after enrollment, coordinators reviewed records for disease and treatment information. Records were also reviewed to determine if patients had been offered a therapeutic clinical trial since enrollment and, if so, their decision regarding participation. There was no blinding of study personnel or treating physicians to intervention assignment. Standardized training and monitoring procedures were implemented for all site coordinators.

Immediately after random assignment, patients in the MP condition viewed a 10-minute DVD[9]; they were then given a copy to keep plus a 16-page booklet based on the DVD reinforcing key points. Procedures used to develop the DVD and booklet have been described elsewhere.[9a] In brief, a three-phase approach used to develop other psychoeducational interventions[10,11] was implemented, in which: first, interviews with key stakeholders were used to inform content development; second, early versions of the intervention were pretested with patients to ensure content suitability and understandability; and third, the final version of the intervention was evaluated with patients for satisfaction and salience. The overall objective was to prepare patients for possible discussion and decision making about participation in a therapeutic

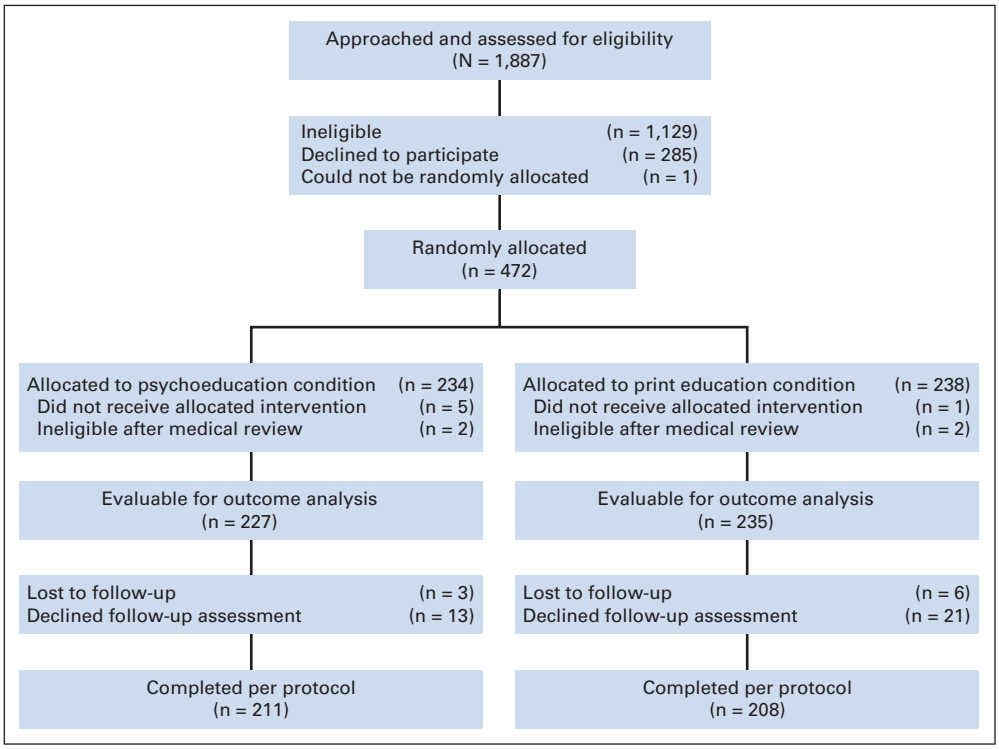

Fig 1. CONSORT diagram.

clinical trial. Primary goals were to foster an open-minded attitude about clinical trial participation, motivate patients to learn more about clinical trials available to them, and lay the groundwork for informed decision making about participation using examples from other patients' experiences. Accordingly, in addition to providing information, the DVD addressed misperceptions and concerns about clinical trials (eg, they are offered only as a last resort) and described how clinical trials can result in more effective cancer treatments. Patients and physicians served as spokespersons and provided recommendations that patients ask their physicians about clinical trials and, if eligible, consider carefully whether to participate. To communicate this last point, the DVD featured patients describing reasons why they did or did not choose to participate in a clinical trial.

Patients in the PE condition were asked to read a 16-page National Cancer Institute booklet (entitled "Taking Part in Cancer Treatment Research Studies") and were given a copy to keep. This booklet consists primarily of educational information about the nature and conduct of clinical trials.

Study Measures

Before the study, the investigators developed and pilot tested five self-report outcomes measures, described in the protocol. Procedures used included literature review, revision/adaptation of existing items, expert appraisal, cognitive interviewing with patients to confirm understandability, and pilot testing with patients for reliability and validity.[12] Each was administered during the baseline and follow-up assessments.

Positive attitudes toward clinical trials (eg, "being in a clinical trial benefits other patients") and negative attitudes (eg, "being in a clinical trial is likely to cause a patient harm") were measured using 20 items with response options ranging from strongly agree (1) to strongly disagree (5). After reverse coding negatively worded items, an average score was calculated (possible range, 1 to 5).

Knowledge about clinical trials was measured using 13 items. Response options were true, false, or don't know. Total score represented the number of items answered correctly (possible range, 0 to 13).

Perceived ability (ie, self-efficacy) to carry out actions involved in making an informed decision about clinical trial participation (eg, "I think I could get the information I need to decide whether to be in a clinical trial") were assessed using nine items with response options ranging from strongly agree (1) to strongly disagree (5). After reverse coding negatively worded items, an average item score was calculated (possible range, 1 to 5).

Receptivity to learning more about clinical trials was measured using one item (ie, "If you were offered a cancer clinical trial, would you be willing to hear more information about it?"), with response options ranging from definitely yes (1) to definitely no (5). Scores were reverse coded, so higher scores indicate greater receptivity (possible range, 1 to 5).

Willingness to participate in clinical trials was measured using one item ("If a cancer clinical trial were offered to you, would you agree to take part in it?"), with response options ranging from definitely yes (1) to definitely no (5). Scores were reverse coded, so higher scores indicate greater receptivity (possible range, 1 to 5).

Statistical Analyses

Before conducting the main analyses, participants' demographic and clinical characteristics were evaluated for possible differences by intervention condition using the Wilcoxon or χ^2 test as appropriate. Separate analyses of covariance were conducted to examine effects of intervention assignment on the five outcomes. In each analysis, baseline score for the outcome and study site (Moffitt Cancer Center *v* other) were included as covariates. *P* values for these five analyses were calculated using the Holm adjustment for multiple comparisons,[13] which involves rank ordering the raw *P* values (from smallest to largest) and then multiplying each raw *P* value by the inverse of its rank. The resulting *P* value (or adjusted *P* value for previous rank if larger) is then evaluated against a $P < .05$ significance criterion. Analyses were based on all eligible patients who received their allocated intervention (n = 462); multiple imputation[14] was used to address missing follow-up data on all five outcomes (n = 41), two outcomes (n = 1), or one outcome (n = 1) for 43 patients. Observed effect sizes were computed with Hedges' method,[15] using follow-up means for each intervention condition and the pooled standard deviation. Analyses of intervention effects were also performed for the 419 patients with no missing data. On the basis of observed results, McNemar's tests were performed to evaluate changes within each intervention condition on a dichotomous index of willingness to participate. In addition, χ^2 analysis was performed to evaluate intervention effects on participation in therapeutic clinical trials among 58 participants offered a therapeutic clinical trial. Finally, on the basis of the pattern of observed results, mediational analysis was conducted to examine whether attitudes explained intervention effects on willingness to participate in clinical trials. Path coefficients for the mediator model and bootstrap CIs for effects were estimated to determine the significance of a potential mediator using methods described by Preacher et al.[16] Assuming 90% of patients recruited would provide evaluable data, the accrual target was 480 participants, which would yield 80% power to detect an effect size of 0.3

Table 1. Participant Demographics and Clinical Characteristics by Intervention Condition

Characteristic	MP Condition (n = 234) No.	%	PE Condition (n = 238) No.	%	*P**
Age, years					.451
Mean	61.9		62.5		
SD	11.2		10.7		
Time since diagnosis, months					.495
Mean	8.1		7.7		
SD	25.2		24.5		
Sex					.346
Male	84	35.9	96	40.3	
Female	150	64.1	142	59.7	
Education					.770
High school or less	77	32.9	75	31.5	
College	155	66.2	162	68.1	
Missing	2	0.9	1	0.4	
Race					1.000
White	212	90.6	214	89.9	
Nonwhite	22	9.4	23	9.7	
Missing	0	0.0	1	0.4	
Ethnicity					.623
Hispanic	9	3.8	7	2.9	
Non-Hispanic	213	91.0	222	93.3	
Missing	12	5.1	9	3.8	
Disease stage					.192
0 to III	176	75.2	161	67.6	
IV	46	19.7	60	25.2	
Unstaged/not applicable	12	5.1	17	7.1	
Cancer type					.772
Breast	61	26.1	57	23.9	
Lung	35	15.0	33	13.9	
Pancreatic	30	12.8	36	15.1	
Multiple myeloma	26	11.1	21	8.8	
Other	81	34.6	91	38.2	
Missing	1	0.4	0	0.0	
Chemotherapy in last year					.261
No	200	85.5	194	81.5	
Yes	34	14.5	44	18.5	
Study site					.771
Moffitt Cancer Center	84	35.9	82	34.5	
Other sites	150	64.1	156	65.5	

Abbreviations: MP, multimedia psychoeducation; PE, print education; SD, standard deviation.

**P* values calculated using Wilcoxon sum rank tests for continuous variables and χ^2 tests for categorical variables. Missing levels were excluded from calculation of *P* values.

with a two-tailed $P < .02$ significance level for the main analyses; the $P < .02$ criterion reflects the average adjusted P value based on the Holm method for five comparisons at the $P = .05$ level.

RESULTS

Between July 2, 2009, and March 1, 2011, 472 patients were enrolled and randomly assigned. Patient participation and flow are depicted in a CONSORT diagram (Fig 1). Sixty-two percent of eligible patients participated. Demographics and clinical characteristics of randomly assigned participants are listed in Table 1. There were no significant differences between intervention conditions regarding these characteristics.

A significant difference was observed for the primary end point of attitudes toward clinical trials ($P = .016$; Table 2), reflecting an effect size of 0.46 that favored the MP condition. Inspection of data for patients who completed per protocol showed that although attitudes tended to become more positive over time in both conditions, consistent with the statistical difference, they improved by 6% in the MP condition versus 4% in the PE condition (Table 3).

There were no significant differences by intervention condition for knowledge, self-efficacy, or receptivity to learning more about clinical trials. A statistically significant difference was observed for willingness to participate in a clinical trial ($P = .011$; Table 2), reflecting an effect size of 0.33 that favored the MP condition. Inspection of data for patients who completed per protocol showed that although willingness to participate tended to decline over time in both conditions, consistent with the statistical difference, it declined by 11% in the PE condition versus 4% in the MP condition (Table 3).

The same pattern of significant differences was evident in analyses based on 420 patients who completed per protocol. To more closely examine changes in willingness to participate, responses of these patients were dichotomized into positive scores (definitely yes or probably yes) and negative/neutral scores (definitely no, probably no, or unsure). Willingness to participate declined over time in the PE condition ($P < .001$); it did not change in the MP condition ($P = .768$). Reflecting these differences, willingness remained positive among 61% of PE participants and 83% of MP participants.

Thirty-one MP participants and 27 PE participants were offered participation in a therapeutic clinical trial after recruitment. The percentages of patients in each condition who agreed to participate were not significantly different (MP, 71%; 95% CI, 52% to 86%; PE, 52%; 95% CI, 32% to 71%; $P = .13$).

On the basis of the significant results for the main analyses, additional analyses were performed examining whether attitudes mediated the relationship between intervention assignment and willingness to participate (Fig 2). Regression analyses confirmed intervention assignment was significantly related to attitudes ($a = 0.19$; SE = 0.04; $P < .001$) and willingness to participate ($c = 0.27$; SE = 0.09; $P = .003$) and showed attitudes were significantly related to willingness to participate ($b = 0.88$; SE = 0.09; $P < .001$). The lack of significance for the effects of intervention assignment on willingness to participate on controlling for attitudes ($c' = 0.11$; SE = 0.09; $P = .216$) is consistent with the presence of mediation. This finding was confirmed by the presence of a significant indirect effect of intervention assignment on willingness to participate using bootstrapping methods (estimated at 0.168; 95% CI, 0.088 to 0.248).

Table 3. Observed Baseline and Follow-Up Scores for Study Outcomes

Outcome	MP Condition (n = 211) Mean	MP Condition (n = 211) SD	PE Condition (n = 208) Mean	PE Condition (n = 208) SD
Attitudes toward clinical trials*				
Baseline	3.53	0.46	3.39	0.41
Follow-up	3.74	0.47	3.53	0.45
Knowledge about clinical trials†				
Baseline	5.98	2.22	5.65	2.08
Follow-up	7.99	1.74	7.59	2.16
Self-efficacy for clinical trial decision making*				
Baseline	4.01	0.46	3.94	0.47
Follow-up	4.20	0.44	4.13	0.48
Receptivity to clinical trial information*				
Baseline	4.58	0.64	4.53	0.71
Follow-up	4.33	0.83	4.24	0.95
Willingness to participate in clinical trial*				
Baseline	3.94	0.82	3.90	0.86
Follow-up	3.78	0.88	3.47	0.99

NOTE. Means and SDs are for patients completing per protocol.
Abbreviations: MP, multimedia psychoeducation; PE, print education; SD, standard deviation.
*Possible range, 1 to 5.
†Possible range, 0 to 13.

Table 2. Adjusted Follow-Up Scores for Study Outcomes and Results for Analyses of Intervention Effects

Outcome	MP Condition (n = 227) Mean†	MP Condition (n = 227) 95% CI	PE Condition (n = 235) Mean†	PE Condition (n = 235) 95% CI	P*
Attitudes toward clinical trials‡	3.69	3.64 to 3.75	3.58	3.53 to 3.64	.016
Knowledge about clinical trials§	7.91	7.66 to 8.15	7.62	7.37 to 7.78	.353
Self-efficacy for clinical trial decision making‡	4.18	4.12 to 4.24	4.14	4.08 to 4.19	.645
Receptivity to clinical trial information‡	4.30	4.19 to 4.41	4.25	4.14 to 4.36	.645
Willingness to participate in clinical trial‡	3.75	3.64 to 3.86	3.50	3.38 to 3.61	.011

Abbreviations: MP, multimedia psychoeducation; PE, print education.
*P values based on analyses of covariance comparing differences in adjusted follow-up means and calculated using Holm adjustment for multiple comparisons.
†Adjusted means estimated from analysis of covariance model.
‡Possible range, 1 to 5.
§Possible range, 0 to 13.

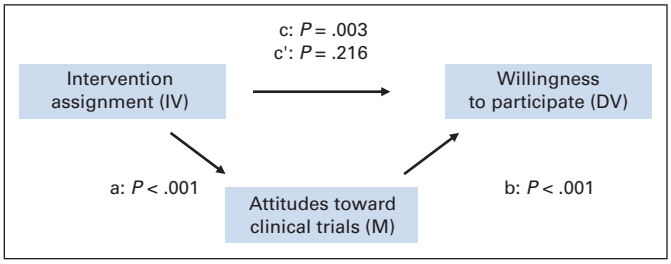

Fig 2. Test of attitudes toward clinical trials as mediator of relationship between intervention assignment and willingness to participate in clinical trials. *P* values based on tests of significance of regression coefficients. a, direct effect of independent variable (IV) on mediator (M); b, direct effect of M on dependent variable (DV); c, direct effect of IV on DV; c′, indirect effect of IV on DV.

DISCUSSION

Results demonstrated the benefits of providing patients with a brief multimedia psychoeducational intervention focused on changing attitudes about clinical trial participation. Compared with patients who received printed educational material, patients who received a multimedia intervention that included printed material developed more positive attitudes toward clinical trials. In addition, patients who received the intervention maintained greater willingness to participate in clinical trials, as reflected on both continuous and dichotomous indices. Findings also showed that beneficial effects of psychoeducation on willingness to participate could be explained by its positive impact on attitudes toward clinical trials.

This pattern of results may explain why many other interventions have not demonstrated a beneficial impact on participation in clinical trials.[2] In several previous studies, the focus was on providing educational materials primarily to increase knowledge about clinical trials[18-20] rather than to change attitudes. In these studies, receipt of educational materials produced improvements in knowledge but did not yield higher rates of clinical trial participation.[18-20] Although there are clear benefits to patients being more knowledgeable about clinical trials, increases in knowledge do not seem to result in increases in willingness to participate.

Although change over time in willingness to participate favored psychoeducation in this study, the finding that it resulted in less of a decline rather than more of an improvement relative to PE was unexpected. The reason for the overall negative direction of change in willingness to participate is not immediately apparent. One possible explanation may involve the fact that most patients in the current study were not offered a clinical trial. Consequently, they may have devalued clinical trial participation at the follow-up assessment to justify to themselves that their conventional treatment constituted optimal care. The process of devaluing something to justify a course of action has been termed cognitive dissonance reduction[21] and is believed to be motivated by the desire to maintain self-esteem.[22]

In contrast to significant findings for attitudes and willingness to participate, there were no effects of intervention assignment on knowledge about clinical trials, self-efficacy for clinical trial decision making, or receptivity to clinical trial information. The lack of an intervention effect on knowledge is perhaps not unexpected, because both study conditions included information about clinical trials; reflecting this content, approximately two additional items were answered correctly at the follow-up assessment in both study conditions. The absence of other effects is less easily explained. Possibilities include overall increases in self-efficacy and decreases in receptivity across conditions that overrode the effects of intervention assignment or the lack of efficacy of psychoeducation in influencing these outcomes.

The current study possesses several strengths. These include a relatively large and heterogeneous sample, multiple recruitment sites, and recruitment of patients who had not been asked previously to participate in a therapeutic clinical trial. There are, however, several weaknesses. First, the study used newly developed measures to assess the five self-reported outcomes and single-item measures to assess two of these outcomes. Second, there is potential for findings to be biased based on the fact that 38% of eligible patients declined to participate in the current study. Third, participants in the two conditions received different booklets, thus precluding evaluation solely of the DVD. Fourth, observed effect sizes for attitudes and willingness to participate were in the small to medium range according to a commonly used metric.[23] Although its effects were modest, the intervention has the potential to reach a large number of patients and thus have broad impact, because it requires relatively little time, effort, and resources to deliver.[24]

Findings from the current study support conducting additional evaluations of this intervention. One direction for future research will be to examine its impact on clinical trial decision making with patients eligible for a therapeutic clinical trial. In the present study in which this characteristic was not an eligibility criterion, only 13% of patients were offered participation in a therapeutic clinical trial in the 6 weeks after study enrollment. Although the current study design does not permit conclusions to be drawn about the effects of intervention assignment on clinical trial participation, the participation rate was found to be 19% higher in the MP condition compared with the PE condition. It should be noted this difference was not statistically significant and was based on a small subsample of patients. Equally important as evaluating the impact on participation rates, a study of patients eligible for a therapeutic clinical trial would provide an opportunity to evaluate the effects of the intervention on the quality of patients' decision making. Key elements to evaluate in this regard, as suggested by the Ottawa Decision Support Framework,[25] would include the accuracy of patients' understanding of the potential benefits and risks of a trial, the extent of decisional conflict and regret patients experience, and consistency between the decision made and patients' values and preferences.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.
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Manuscript writing: All authors
Final approval of manuscript: All authors

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